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|  | APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
|--|---|-------------|----------------------|---------------------------------|------------------|
|  | 10/506,459  | 12/06/2004  | Thomas Albert Engler | X-15654                         | 9960             |
|  | 25885 7590 04/16/2007<br>ELI LILLY & COMPANY<br>PATENT DIVISION |             |                      | EXAMINER  COLEMAN, BRENDA LIBBY |                  |
|  |   |             |                      |                                 |                  |
| P.O. BOX 6288<br>INDIANAPOLIS, IN 46206-6288 |   |             |                      | . ART UNIT                      | PAPER NUMBER     |
|  |   |             |                      | 1624                            |                  |
| _  |   |             |                      |                                 |                  |
|  | SHORTENED STATUTORY PERIOD OF RESPONSE                          |             | NOTIFICATION DATE    | DELIVERY MODE                   |                  |
| 31 DAYS                                      |   | DAYS        | 04/16/2007           | ELECTRONIC                      |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/16/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

A

|   | Application No.  | Applicant(s)                 |  |  |  |  |
|---|--|------------------------------|--|--|--|--|
|   | 10/506,459   | ENGLER ET AL.                |  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit                     |  |  |  |  |
|   | Brenda L. Coleman  | 1624                         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |                              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |                              |  |  |  |  |
| Status  |  |                              |  |  |  |  |
| 1) Responsive to communication(s) filed on  | Responsive to communication(s) filed on                                    |                              |  |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) This  | ☐ This action is <b>FINAL</b> . 2b)☐ This action is non-final.             |                              |  |  |  |  |
| 3) Since this application is in condition for allow   | ance except for formal matters, pro  | secution as to the merits is |  |  |  |  |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |                              |  |  |  |  |
| Disposition of Claims   | •  |                              |  |  |  |  |
| <ul> <li>4)  Claim(s) 1-10 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) 1-10 are subject to restriction and/or election requirement.</li> </ul>  |  |                              |  |  |  |  |
| Application Papers  |  |                              |  |  |  |  |
| <ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>   |  |                              |  |  |  |  |
| Priority under 35 U.S.C. § 119  |  | •                            |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |                              |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ite                          |  |  |  |  |

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## **DETAILED ACTION**

Claims 1-10 are pending in the application.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms a 1,4-diazepine ring.

Group II, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms a 1,5-diazepine ring.

Group III, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms a 1,4-diazonine ring.

Group IV, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where  $-(CH_2)_m$ -W-X-Y-R- forms a 1,6-diazonine ring.

Group V, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where  $-(CH_2)_m$ -W-X-Y-R- forms a 1,5-diazonine ring.

Group VI, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms a pyrimidine ring.

Group VII, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I where  $-(CH_2)_m$ -W-X-Y-R- forms a 1,4-diazocine ring.

Group VIII, claim(s) 1-3 and 6-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms a piperidine ring.

Group IX, claim(s) 1-3 and 6-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms an azepine ring.

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Group X, claim(s) 1-3 and 6-10, drawn to the compounds, compositions and method of use of the compounds of formula I where -(CH<sub>2</sub>)<sub>m</sub>-W-X-Y-R- forms an 1,5-oxazepine ring.

Group XI, claim(s) 1-10, drawn to the compounds, compositions and method of use of the compounds of formula I not embraced by the Groups listed above.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the inventions of Groups I-XI are drawn to structurally dissimilar compounds, compositions and method of use of the compounds of formula I. They are made and used independently. One does not require the other for their use. If, say, the pyrrolo[3,2,1jk][1,4]benzodiazepines of Group I, were anticipated, applicants would not acquiesce in the objection of any of the Groups II-XI there over or vice-versa and, thus, they are not linked to the same or corresponding special technical features.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Tentative election of a single species within the elected group is further required.

If Group XI is elected further restriction may be required.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brenda L. Coleman

Primary Examiner Art Unit 1624

April 10, 2007